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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,446	06/24/2003	Kelly S. Stack	STK-001	9380
47713	7590	11/17/2006	EXAMINER	
<b>IMPERIUM PATENT WORKS</b> P.O. BOX 587 SUNOL, CA 94586				SONNETT, KATHLEEN C
		ART UNIT		PAPER NUMBER
				3731

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/602,446	STACK, KELLY S.
	Examiner Kathleen Sonnett	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 September 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-20 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Arguments***

1. Applicant's arguments filed 9/11/2006 have been fully considered but they are not persuasive.
2. Applicant argues that Wilson et al. (US 2004/0098073) does not disclose all of the limitations of amended claim 1, in particular, the plural layers on a wrist facing side. Applicant argues that the fabric layer (112) is not part of the thermal treatment pack (100) of Wilson. However, the examiner respectfully disagrees. Wilson et al. does disclose that the fabric layer can be placed around the limb where the thermal pack is to be positioned, but also discloses that the fabric layer can be attached to the thermal pack by hook and loop fasteners (fig. 6 and [0050]). When the fabric layer is hooked onto the thermal pack, the bracelet has plural layers on the wrist facing side and a single layer of the fabric on the outer side.
3. It is noted that layers 104 and 105 of the device of Wilson et al. are not a fabric but rather a flexible material of polymeric film and therefore, Wilson et al. alone no longer anticipates amended claim 1. Regarding claims 11 and 19, the thermal pack of Wilson does contain capsules that are adapted to allow an infant to suck on the capsule. That is, if the thermal pack of Wilson et al. is put on an infant's wrist, the infant can suck on one of the capsules contained within the layers 104 and 105 since the outer layer of the thermal pack is a flexible material.
4. Regarding applicant's arguments concerning Werton (U.S. 5,160,344), the language of the original claims only necessitate that the device is *capable* of being attached to a wrist of an infant and that an infant can suck on capsules contained in the device. Therefore, the device must be an annular member that can be attached to a wrist and that can house capsules. The device of Werton clearly meets these limitations. The fact that Werton does not disclose wearing

the device on the wrist of the infant does not make the claimed invention distinguishable over Werton. That is, depending on the size of the infant, for example a preemie, the device would fit over the infant's hand so that it is attached to the infant's wrist or alternatively it could be snapped onto the infant's bracelet using the interconnection system.

5. Examiner acknowledges that the amendments have overcome the previously presented 35 U.S.C 101 rejections.

#### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. **Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the specification only discloses that the capsules are "smaller than the size of an infant's mouth in order to allow the infant 13 to suck on individual capsules through the fabric" [0021]. The specification does not disclose that the capsules are approximately the size of an infant's mouth.

#### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 1-4 and 6-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over McKay (U.S. 5,305,470) in view of Wilson et al. (2004/0098073). McKay discloses an apparatus comprising a bracelet (fig. 1), the bracelet enclosing a volume and adapted to be attached around an infant's wrist, wherein the bracelet has a wrist facing side (16) and an outer side (18) opposite the wrist facing side, and wherein the bracelet is made of plural layers of fabric on the wrist-facing side and a single layer of the fabric on the outer side (col. 2 ll. 34-42; col. 3 ll. 44-45; example shown in fig. 5 "58"). McKay discloses that an ice pack filled with gel (col. 3 ll. 60-62) can be inserted into the fabric bracelet but does not disclose that a plurality of capsules are within the volume, each of the plurality of capsules containing a substance that is liquid at room temperature.

10. However, Wilson et al. discloses that it is old and well known to include water-filled capsules within a temperature retaining fluid to extend the period of time during which the thermal pack remains cold. Specifically, Wilson et al. discloses using small spherical water filled capsules. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of McKay to include water-filled capsules within the gel as made obvious by Wilson et al. in order to extend the period of time during which the thermal pack remains cold.

11. Regarding claim 2, the bracelet is elastic (col. 3, ll. 44-45).

12. Regarding claim 6, the flexible, elastic fabric material that makes up the outer layer of McKay's device along with the cold pack that remains flexible even after being cooled to below the freezing point of water (col. 3 ll. 60-62) would allow an infant to suck on one of the plurality of capsules through the fabric and cold pack.

13. Regarding claim 9, the plural layers are less thermally conductive than the single layer of fabric (col. 4 ll. 45-50).

14. Regarding claim 11, modified McKay discloses a method comprising enclosing a substance in a bracelet that is made of fabric, attaching the bracelet to the wrist of a user, and insulating the wrist of the user from the temperature of the substance. As made obvious by Wilson et al., water-filled capsules are housed in the gel of the cold pack of the bracelet. The capsule is adapted to allow the infant to suck on the capsule through the fabric, as the fabric and cold pack materials are flexible. McKay does not expressly disclose attaching the bracelet to the wrist of an infant.

15. However, Wilson et al. discloses that the wearer of a cooling device may be a child [0046], which defines an age range that includes infants and it would be obvious to one of ordinary skill to employ the cooling device of McKay on an infant since thermal treatment is useful for people of all ages.

16. Regarding claim 12, the insert is a cold pack and has therefore been cooled.

17. Regarding claims 13, 14, and 16 see col. 3 ll. 42-54 and figs. 1 and 2.

18. Regarding claims 17 and 18, see col. 2 ll. 35-39.

19. Regarding claim 19, modified McKay discloses water filled capsules containing a cooled substance and means for attaching the capsules to a wrist of an infant (fabric wrist band), for insulating the wrist of the infant from the cooled substance (both inside layers of fabric), and for allowing the infant to suck on the capsule through the attachment means.

20. Regarding claim 20, see col. 3 ll. 50-51.

21. Regarding claims 3 and 15, modified McKay includes a plurality of water-filled capsules but Wilson et al. does not expressly disclose that the water-filled capsules have a rigid covering. However, Wilson et al. further discloses that other free-flowing solid structures such as metal or glass spheres can be used in place of the water-filled capsules ([0042]). The structures disclosed by Wilson et al. are rigid structures and therefore, it would have been obvious to one

of ordinary skill in the art to make the covering of the water-filled capsules rigid in order to withstand the freezing-thawing process and pressure applied by the user.

22. Regarding claims 7 and 8, McKay does not disclose how the bracelet is formed. However, Wilson et al. discloses some manufacturing techniques for making a wrist band. In particular, Wilson discloses starting out with a square piece of fabric, forming a tube by sewing two of the edges together to form a first seam, inverting the tube as seen in fig. 7c, and finally sewing a seam that closes the tube by sewing edges 116 and 118 together. This technique requires only two seams. Employing this technique in the device of McKay requires only slight modifications that are well within the knowledge of one of ordinary skill in the art. McKay has an additional insulating layer of fabric on the inside facing surface of the device. Using the technique of Wilson et al., only one additional seam is needed to connect the insulating layer to the fabric. An insulating layer covering the bottom half of the fabric layer square can be laid on top of the sheet of fabric and a single seam can attach the insulating layer to the sheet of fabric (along the midline of 113). The remaining steps are performed as disclosed by Wilson et al., with the remaining two seams going through both the insulating layer and the fabric layer. Because McKay discloses that the insulating layer is on the wrist facing side of the device, it would be obvious to one of ordinary skill in the art to form the tube shown in fig. 7b with the insulating layer on the outside. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of McKay to use the method of manufacturing as disclosed by Wilson et al. with minor changes to account for the presence of an insulating fabric layer on the wrist facing surface of the device since the two devices are similar in structure.

23. Regarding claim 8, two of the three seams separate the wrist-facing side from the outer side. That is, the first seam is at the top of the tube (where 116 and 118 are attached, see fig.

7a) and the other seam is at the bottom of the tube (where the insulating layer was initially attached to the fabric layer square).

24. Regarding claim 10, the modified device of McKay includes spherical capsules that are roughly the size of peas. The size of the capsules is chosen such that they are small enough to allow the thermal treatment pack to comfortably conform to a user's limb ([0042] of Wilson et al.) Approximately the size of an infant's mouth is most likely larger than a pea, but still quite small. At the time the invention was made, it would have been an obvious matter of design choice for a person of ordinary skill in the art to employ slightly larger capsules such as capsules approximately the size of an infant's mouth since this is still small enough to allow for the thermal treatment pack to comfortably conform to a user's limb. Since this is the only advantage of smaller capsules given by Wilson et al., slightly larger capsules that would perform the function of cooling the gel while still allowing the treatment pack to comfortably conform to a user's limb as well as pea sized capsules is considered merely a design consideration. Therefore, it would have been *prima facie* obvious to further modify McKay to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of McKay.

25. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over McKay in view of Wilson et al. as applied to claim 1 above, and further in view of Brink (U.S. 5,843,145). Modified McKay discloses the invention substantially as stated above, including the presence of water-filled capsules enclosed within the bracelet. Modified McKay does not expressly disclose that the water-filled capsules are frozen. However, as disclosed by McKay, the gel that surrounds the capsules advantageously does not become a hard solid after being cooled to below the freezing point of water (col. 3 ll. 60-62), which indicates that the bracelet will be cooled to these temperatures. The water-filled capsules would then be frozen. Furthermore, Brink discloses that

it is old and well known in the art to have capsules that hold frozen liquid dispersed in a gel. The capsules serve to provide means for cooling the gel after the cold (such as by a freezer) is no longer applied to the temperature pack (col. 4 lines 20-32 and 38-50). Therefore, it would have been obvious to one of ordinary skill in the art to freeze the water-filled capsules as made obvious by Brink in order to provide a means for cooling the gel that surrounds the capsules after the bracelet has been chilled and removed from the cold source.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



GLENN K. DAWSON  
PRIMARY EXAMINER

KCS  
11/9/2006